Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

FROM: Orthopedic Surgical Manufacturers Association (OSMA)

DATE: October 26, 1999

SUBJECT: **DOCKET NO. 99D-2212**: Comments on FDA Draft Guidance – "Guidance on Quality System Regulation Information for Various PreMarket Submissions"

Listed below are OSMA's comments on the above referenced draft guidance document.

General Comments:

This document is supposedly intended to clarify the QSR-related documentation requirements for supporting premarket submissions. However, it appears to go beyond this by not only clarifying documentation support for submissions, but also by articulating design control and QSR requirements. Furthermore, it appears to establish some requirements/expectations that exceed design control requirements under 820.30 and other QSR requirements. This document should be oriented not to define or establish design control requirements, but rather to identify the elements of design controls that should be addressed in order to support submissions and provide evidence of compliance with design control and other QSR requirements. Moreover, the need for this guidance document as it currently exists is questionable given that it essentially attempts to articulate requirements for two areas – fulfillment of QSR requirements and premarket submissions. Clarification and articulation of QSR requirements should be accomplished in a guidance document specific to that topic, and supporting documentation requirements for submissions should be addressed in guidance documents that outline the submission content and format requirements for a specific type of submission.

99D-2212 C3

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Specific Comments:

On page 4, delete #2. This is unnecessary and redundant given that risk analysis is addressed in #3 on page 4. Furthermore, the wording of #2 implies requirements/expectations that exceed the requirements of the QSR regulations under 820.30.

On page 4, # 3, change the first bulleted point from "...and assign responsibility for implementation of each..." to "...and where applicable assign responsibility for the implementation of, each...". This change is warranted given the inclusion of "Interfaces" in (i) for which it may not be possible to assign responsibility for implementation.

On page 5 in the first bulleted point describing the requirements of the plan, the requirements are much more detailed and specific than the regulation (e.g. the requirement here to "outline the timing strategy") and all of the requirements may not apply in every case. In addition, this paragraph appears to be inconsistent with the first sentence in #3 on page 4 which allows for simply a summary of the plan. Thus, the wording and expressed requirements of the first bulleted point on page 5 should be deleted or reduced to simply specify/require descriptive information on the plan that provides evidence of compliance with design controls.

On page 5, in the first bulleted point for # 4, insert "where applicable" after or before "the following relevant aspects should be addressed:" given that not all the listed aspects of design input will be applicable in every case (e.g. electromagnetic compatibility, toxicity and biocompatibility)

On page 5, delete # 5 as it is redundant with # 4(b) on page 5

On page 6, delete # 6 as it is redundant with # 4(h) on page 5

On page 6, # 8, change "A written copy of the written procedures..." to "A copy of the written procedures..."

On page 7, delete # 15. The reference to a "risk management program" here appears to establish a requirement that exceeds the regulations, and the remaining part of # 15 is already addressed in # 2 and # 3.

On page 8, # 1 under "Manufacturing Dossier", delete the first paragraph as it implies a requirement for a quality manual, which is not required by the QSR. The requirement should be limited here (as is expressed in the bulleted paragraph under # 1) to an outline of the quality system documentation for the manufacturing facility that will be responsible for manufacturing the device. Also, in the bulleted paragraph under # 1, change the last sentence to read "The development of a quality manual that is consistent with ISO 10013-1195 "Guidelines for Developing Quality Manuals" would satisfy the quality system documentation requirement"

Thank you for your consideration of our comments.

Sincerely yours,

Lonnie Witham
OSMA Task Force Chairman

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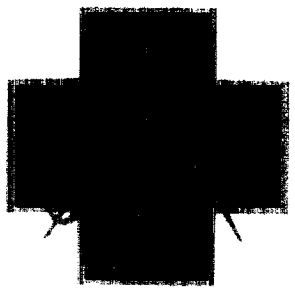

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